SEP 16 2004

Attachment D: 510(k) Summary

K042281

Immunodiagnostic Development Center
1000 Lake Hazeltine Drive
Chaska, Minnesota 55318-1084

Applicant:	Beckman Coulter, Inc. Immunodiagnostics Development Center 1000 lake Hazeltine Drive Chaska, MN 55318
Contact Person:	Barbara Stegmeier, RAC Principal Consultant Phone: 952.368.7648 Fax: 952.368.7610
Date Prepared:	August 23, 2004
Trade Name:	Access® HYPERsensitive hTSH Assay
Product Classification and Code:	II - JLW
Predicate Device:	Access® HYPERsensitive hTSH Assay – K023093, K954825, K925637
Device Description:	The Access® hTSH assay consists of the reagent pack and calibrators. Other items needed to perform the assay include the diluent, substrate and wash buffers.
Intended Use:	The Access® hTSH Assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of human thyroid-stimulating hormone (thyrotropin, hTSH) levels in human serum and plasma using the Access® Immunoassay Systems.
Summary of Technological Characteristics:	The assay has been modified to allow performance of a "2nd generation" test (≤ 20% CV at 0.1 µIU/mL) in addition to the exiting "3rd generation" test (≤ 20% CV at 0.01-0.02 µIU/mL). The 2nd generation test requires a smaller sample size, has a shorter incubation time and provides results in less time than the 3rd generation test.
Conclusion:	The modified Access® hTSH assay is substantially equivalent to the previously cleared Access® hTSH assays.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 16 2004

Ms. Barbara Stegmeier
Principal Consultant
Beckman Coulter, Inc.
Immunodiagnostic Development Center
1000 Lake Hazeltine Drive
Chaska, MN 55318-1084

Re: k042281
Trade/Device Name: Access HYPERsensitive hTSH Assay
Regulation Number: 21 CFR 862.1690
Regulation Name: Thyroid stimulating hormone test system
Regulatory Class: Class II
Product Code: JLW
Dated: August 23, 2004
Received: August 24, 2004

Dear Ms. Stegmeier:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042281

Device Name: Access HYPERsensitive hTSH Assay

Indications for Use:

The Access HYPERsensitive hTSH Assay provides in vitro quantitative measurement of the human thyroid-stimulating hormone (hTSH) in human serum or plasma. The Access HYPERsensitive hTSH Assay is indicated for use with patients where an assessment of their thyroid status is desired. This assay is capable of providing 3rd generation (HYPERsensitive hTSH) and/or the 2nd generation (Fast hTSH) results.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol C. Benson

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K042281